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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,078	08/26/2003	Terry L. Ray	4042-A4	3377

29370 7590 01/26/2007  
ROBERT A. PARSONS  
4000 N. CENTRAL AVENUE, SUITE 1220  
PHOENIX, AZ 85012

EXAMINER
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ALI, SHUMAYA B

ART UNIT	PAPER NUMBER
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3771

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/26/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/648,078

Applicant(s)

RAY ET AL.

Examiner

Shumaya B. Ali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 5, 6, 15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 7-11 and 17-20 is/are rejected.
- 7) ☒ Claim(s) 2-4 and 12-14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Claims***

Claims 1-20 are pending in the instant application. Claims 5,6,15, and 16 remain withdrawn as being drawn to a non-elected species.

### ***Response to Amendment***

Amendment to claims filed on 11/13/06 has been acknowledged.

### ***Response to Arguments***

#### **Drawings**

Applicant's arguments, filed on 11/13/06, with respect to drawing objections set forth in the previous office action found persuasive, therefore, the drawing objections have been withdrawn.

#### **Double Patenting**

Applicant's arguments, filed on 11/13/06 with respect to nonstatutory obviousness-type double patenting set forth using U.S. 6,286,510B1 and U.S. 6,371,118B1 have been fully considered, however they are not persuasive. Especially where the Applicant argued, "while the end result of blocking an oviduct is the goal of the both devices, how this result is achieved is different" (see remarks page 10 lines 19-21), is not well taken since the use of the device is not given weight in an apparatus claim. In further arguments Applicant presented, "the present invention as claimed, does not resort to "engaging the oviduct", but in fact is anchored to the uterine cavity wall" (see page 11, lines 2-4), such argument is not well taken because arguments

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once again rely on the use of the apparatus. Applicant further stated that “claimed structure is completely different and does not anchor the device the same manner or does the patent ‘510 suggest this structure” (see page 11, lines 4-6), however Applicant is further reminded that such arguments are not well taken, and considered irrelevant since how the device is being used does not result in structural differences between the instant application and patented claimed structure. Therefore, although Applicant argues that structural differences exists, however those differences are pointed out to be different use of the device, and since the use of the device is not given marital weight in apparatus claims, arguments with respect to the use of the device as presented, see remarks page 11 lines 1-9 are not well taken.

Arguments with respect to US’510B1 presented on page 11, lines 10-21 once again resonated different use of the device rather than the structural differences that can be found in the instant and patented claimed invention, therefore such arguments are not well taken for the above stated reasons.

In further arguments Applicant presented, “the specific structure required for the engaging the uterine tissue is a **peripheral** anchor. This cannot be the case in patent ‘510 since the device requires an engagement element carried by the insert and the insert must pass through the opening and enter the oviduct” (see remark page 12, lines 4-9). However, Applicant’s attention is invited to the claimed invention, which requires a body with peripheral anchor, and US’510-insert and engagement element are respectively recite on the body and peripheral anchor. Therefore, the patented claim anticipates “peripheral anchor” of the claimed invention. Therefore, arguments presented on page 12, lines 4-9 are not well taken.

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In further arguments Applicant requested withdrawal of rejection based on US 6,371,118B1 because “the “insert” of the ‘118 patent does not read on “body” because the “insert” is specifically inserted into the oviduct which is not and cannot be done with the body. “Second portion” does not read on “peripheral anchor” because it is not a peripheral anchor, and cannot accomplish any of the function thereof” (see page 12, lines 10-23). Such arguments are not well taken, because the “insert” is considered the body, and insert’s second portion is considered the peripheral anchor because patented claim 1 states, “second portion including a bridgeable **anchor**”, thus reads on the instant claim recitation of a “peripheral anchor”; the later argument with respect to the functional recitation is not given weight in an apparatus claim, because the argument does not present there is a structural difference exist between the instant and patented claims.

### **35 USC 112 rejections**

Applicant’s arguments, see page 13 lines 1-14, with respect to claim rejection under 35 USC 112 found persuasive, therefore, former rejection to claims 2-4 and 12-14 under 35 USC 112 second paragraph is hereby withdrawn.

### **35 USC 102 (b) rejection**

Applicant argued, “Zeluff teaches using a light adhesive on locator pin 20, but this is an adhesive, not an anchor, and is in the oviduct not on the uterine wall” (page 14 lines 12-14), however structure of the pin 20 by itself is considered an anchor. Therefore, the arguments with respect to “adhesive” as an anchor are not relevant. Further more, arguments with respect to “uterine wall” are irrelevant since “uterine wall” is not supported by the claim.

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In further arguments, Applicant presented “claims 1 and 11 have been amended to include the anchor being inserted into the uterine tissue...not taught by Zeluff” (page 14, lines 17-20) found persuasive, however rejection to claims 1 and 11 based on Zeluff stand since “for insertion into and engaging the uterine tissue” as recited in the amended claims 1 and 11 is considered recitation of intended use of the claimed invention, which must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

**35 USC 103 (a) rejection**

Applicant’s arguments with respect to claims 2 and 12 were found persuasive; therefore rejection to claims 2 and 12 set forth using Zeluff is hereby withdrawn.

Applicant’s arguments, see page 16 lines 3-10 that Zeluff does not teach a biodegradable body is not persuasive, because according to Applicant’s disclosure, body 12 can be constructed of bio-compatible material such as stainless steel, titanium, ceramics or a poly-base material (see specification page 8, lines 15-17), and Zeluff discloses “stainless steel” (see col.7 lines 7-11), therefore, Zeluff anticipates a biodegradable body, thus Applicant’s argument with respect Zeluff not teaching a biodegradable body is irrelevant.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

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application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**Claims 1 and 11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 14 of U.S. Patent No. 6,286,510 B1.**

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 1 and 11 are broader version of the patented claims 1 and 14.

Regarding the broadening aspect of the instant claims 1 and 11, a body considered to read on “insert” cited in col.5 lines 21 and 22 of the patented claim 1, and col.6 lines 10 and 11 of the patented claim 14. The difference between the instant claims 1 and 11 body and the insert in the patented claims 1 and 14 is that instant claims require body having a base with a periphery, however it would have been obvious to consider the bottom of the insert as a base, and further consider the insert to have a periphery since an object of any form inherently has a periphery. Further difference between the instant claims 1 and 11 and the patented claims 1 and 14 is that the recitation of the instant claims, “for insertion into and engaging the uterine tissue leading to the opening and securing the body to the uterine tissue leading to the opening” is excluded from the patented claims, however peripheral anchor of the instant claims is considered obvious over

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“an engagement element” cited in col.5 lines 27 of the patented claim 1, and 28 and col.6 lines 17-19 of the patented claims. Since the patented claims 1 and 14 render obvious the overall claimed structural limitation of the instant claims 1 and 11, any infringement over the patent would also infringe over the instant claims 1 and 11. Hence, the instant claims 1 and 11 do not differ from the scope of the patented claims 1 and 14.

Thus, it is apparent that the more specific patented claims 1 and 14 encompass instant claims 1 and 11. Following the rationale in *In re Goodman*, cited above, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer. Note that since instant claims 1 and 11 are anticipated by patented claims 1 and 14, and since anticipation is the epitome of obviousness, then instant claims 1 and 11 are obvious over patent claims 1 and 14.

**Claims 1 and 11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 11 of U.S. Patent No. 6,371,118 B1.**

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 1 and 11 are broader version of the patented claims 1 and 11.

Regarding the broadening aspect of the instant claims 1 and 11, a body considered to read on “insert” cited in col.6 lines 24 and 25 of the patented claim 1, and col.6 lines 64 and 65 of the patented claim 11. The difference between the instant claims 1 and 11 body and the insert in the patented claims 1 and 11 is that instant claims require body having a base with a periphery, however it would have been obvious to consider the bottom of the insert as a base, and further consider the insert to have a periphery since an object of any form inherently has a periphery.

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Further difference between the instant claims 1 and 11 and the patented claims 1 and 11 is that the recitation of the instant claims, “for insertion into and engaging the uterine tissue leading to the opening and securing the body to the uterine tissue leading to the opening” is excluded from the patented claims, however peripheral anchor of the instant claims is considered obvious over “a second portion” cited in col.6 line 27 of the patented claim 1, and col.6 line 67 of the patented claims. Since the patented claims 1 and 11 render obvious the overall claimed structural limitation of the instant claims 1 and 11, any infringement over the patent would also infringe over the instant claims 1 and 11. Hence, the instant claims 1 and 11 do not differ from the scope of the patented claims 1 and 11.

Thus, it is apparent that the more specific patented claims 1 and 11 encompass instant claims 1 and 11. Following the rationale in *In re Goodman*, cited above, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer. Note that since instant claims 1 and 11 are anticipated by patented claims 1 and 11, and since anticipation is the epitome of obviousness, then instant claims 1 and 11 are obvious over patent claims 1 and 11.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 1,7-11,17,18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zeluff US Patent no. 4,606,336**

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

As to **claim 1**, Zeluff discloses an apparatus for preventing fluid transfer through an opening connecting an oviduct to uterine cavity (see abstract), the apparatus comprising, a body (**fig.2, 12**) having a base (**bottom side of 12 which would be area defined by "D" in figure 2**) with a periphery (**fig.2, 14**); a seal (**22**) carried by the body for overlying and engaging uterine tissue leading to the opening and receiving fibroblast in-growth to create a hermetic seal between the oviduct and the uterine cavity (**col.3 lines 28-32**), a peripheral anchor portion (**20**) extending from the base (**see fig. 2**) for inserting into and engaging the uterine tissue leading to the opening and securing the body to the uterine tissue leading to the opening, the base overlying the opening (**col.5 lines 63-65**). Applicant is reminded the language of indented use such as "for insertion into" is not given weight in an apparatus claim. Zeluff teaches anchor 20, which is capable of being inserted into and engaging the uterine tissue since Zeluff's anchor 20 can be inserted into and engaging the tissues of the reproductive organ (see col.6 lines 17-36).

As to **claim 7**, Zeluff discloses wherein the body supports an engaging member (**fig.11, 58**) that may be grasp by a tool (**figures 5 and 6A, 26**) and which allows the apparatus to be manipulated during installation.

As to **claim 8**, Zeluff discloses wherein the engaging member is carried by an extension of the body (**see fig. 11**).

As to **claim 9**, Zeluff discloses wherein the seal is formed of a biocompatible material that stimulates in-growth of fibroblastic tissue (**col.3 lines 27-32 and 40-43, see claim 5 for "biocompatible"**).

As to **claim 10**, Zeluff does not explicitly disclose wherein the body is fabricated of a biodegradable material. However, according to Applicant's disclosure, body 12 can be

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constructed of bio-compatible material such as stainless steel, titanium, ceramics or a poly-base material (see specification page 8, lines 15-17), and Zeluff discloses “stainless steel” (see col.7 lines7-11), therefore, Zeluff teaches the body is fabricated of a biodegradable material.

**As to claim 11**, Zeluff discloses claimed invention as applied for claim 1.

**As to claim 17**, Zeluff discloses claimed invention as applied for claim 7.

**As to claim 18**, Zeluff discloses claimed invention as applied for claim 8.

**As to claim 19**, Zeluff discloses claimed invention as applied for claim 10.

**As to claim 20**, Zeluff discloses structural limitation as applied for claim 1 required to perform the method steps cited in claim 20. For instance, method step of providing apparatus comprising a body having a base with a periphery, a seal formed of a biocompatible material that stimulates in growth of fibroblastic tissue carried by the body and a peripheral anchor portion extending for the base are all taught by Zeluff (for structural limitations see claims 1 and 10). Furthermore, the method step of positioning the apparatus with the seal overlying and engaging uterine tissue leading to the opening, inserting the peripheral anchor portion into the uterine tissue surrounding a defining the opening, and receiving fibroblastic in growth in the seal to create a hermetic seal between the oviduct and the uterine cavity are taught by Zeluff, see col. 3, lines 27-32, col.4 lines 30-55, and col.6 lines 17-37. Therefore, the method steps cited in claim 20 would have been an obvious result of using the apparatus of Zeluff.

### ***Claim Objections***

Claim 17 is objected to because of the following informalities: status identifier of claim 17 should be “currently amended” not “original”. If no further amendment to claim 17 requires

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in the upcoming remarks, then the status identifier should be “previously presented”.

Appropriate correction is required.

*Allowable Subject Matter*

Claims 2-4, and 12-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

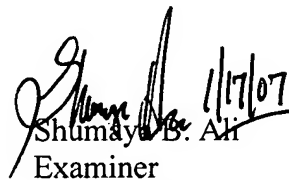
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Shumaya B. Ali  
Examiner

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JUSTINE R. YU  
SUPERVISORY PATENT EXAMINER  
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1/19/07